

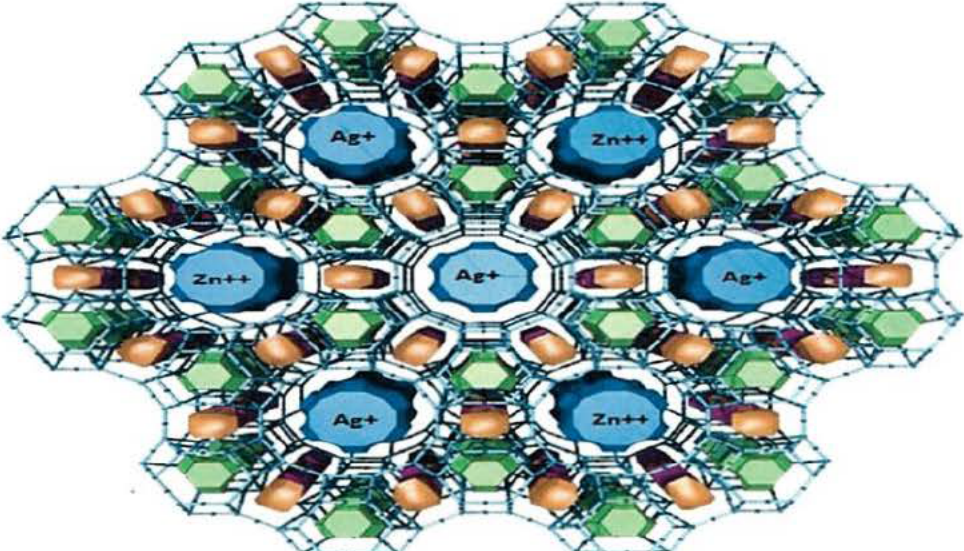
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

September 16, 2015

EPA Reg#: 82415-2		DP Barcode: 404346	
		Submission #:	E-Sub#:
Product name: Bactekiller AZ		Registrant: Fuji Chemical Industries, Ltd Corporation	
Reviewer's name: Salvador Rodriguez		AD/PSB/CTT- Product Chemistry	
Agency due date:		PSB received date: 07/01/15	
CTT received date: 07/01/15		Science received date: 07/01/15	
Formulation type: MUP			
Integrated system: <input checked="" type="checkbox"/>		Non-integrated system: <input type="checkbox"/>	Food use: <input type="checkbox"/> Non-food use: <input checked="" type="checkbox"/>
Action Code:		Date Completed: 09/16/15	
PC Code(s)	CAS #(s)	Active Ingredient Names	% wgt (label)
072501	7440-22-4	Silver	3.5
129015	7440-66-6	Zinc	6.5
			
Test Lab: Fuji Chemical Industries, Ltd.			
MRID(s): 48858302			
Approver: Karen P. Hicks		Approved date: 09/16/15	
Guideline: OPPTS Guideline Table "B" 830.7520 "Particle size, fiber length & diameter distribution"			
Comments:			

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10/07/15

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Antimicrobials Division (AD)

September 16, 2015

MEMORANDUM

Subject: Review for 82415-2
Product Name: **Bactekiller AZ**
DP#: 404346

From: Salvador Rodriguez, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

To: SanYvette Williams
Regulatory Management Branch I
Antimicrobials Division (7510P)

Code:

Two handwritten signatures in black ink. The top signature is smaller and more compact, while the bottom signature is larger and more stylized, with long horizontal strokes.

Date Due:

Applicant: Fuji Chemical Industries, Ltd Corporation

Formulation from Label


<u>Active Ingredient</u>	<u>% by wt.</u>
Silver-Zinc Zeolite: (CAS #: 130328-20-0)	
• Elemental Silver.....	3.5
• Elemental Zinc	6.5

BACKGROUND:

The registrant, Fuji Chemical Industries, Ltd Corporation, has submitted a Confidential Statement of Formula for the basic formulation and the OPPTS Guideline Series 830 Table "B" Series 830.7520" to support the registration for the nano product composite **Bactekiller AZ**. The product chemistry reviewer has received the following documents:

- Confidential Statement of Formula (CSF), dated 04/29/1993, for the basic formulation (Reference).
- Confidential Statement of Formula, dated 09/15/15, for the basic formulation.
- Cover & transmittal letter, dated 06/06/2012. MRID #: 48858300
- OPPTS Guideline, Series 830, Tables "B". Study titled: "Product Chemistry of **Bactekiller AZ**" OCSPP 830.7520 Particle Size". MRID #: 48858302
- Application for pesticide Amendment, dated 06/07/2012.

FINDINGS:

1. The OPPTS Guidelines Group "B" OCSPP 830.7520, product chemistry data requirements applicable to nano particles manufactured-use product have been met. MRID #: 48858302
3. The particle size distribution of Bactekiller AZ, has been determined by the laser Diffraction technology technique Horiba LA-920- circulation, with or w/o Ultrasound. With water as a dispersion medium.
4. 
4. The CSF, dated 09/15/15, for the basic formulation is revised.
5. The nominal concentration of the active ingredient on the revised CSF is consistent with the label.

Manufacturing process information may be entitled to confidential treatment

6. All certified limits meet 40 CFR EPA standard certified limits.

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the Confidential Statement of Formula, dated 09/15/15, for the basic formulation, and the OPPTS Guideline, Series 830.7520 "Particle size, fiber length & diameter distribution" group "B" product chemistry requirements for the disinfectant, algacide, non-integrated, non-food use, end-use product **EPARN: 82415-2 to be acceptable**. The mean diameter particle size has been found to be 2324.2 nm.

830.7520 Particle size, fiber length, and diameter distribution.	A	<p>The particle size distribution of Bactekiller AZ has been determined using Laser Diffraction technology that can detect diameters in the range of 20 nm to 2 mm. In this method, suspended particles diffract incident light at differing angles dependent on the particle size. There are two sets of data for the same product - with and without ultrasound. Ultrasound is used to provide greater dispersion of the particles, which tend to agglomerate. A report of this determination is attached (see Attachment A). As a conclusion of the report, all particles in the Bactekiller AZ product have diameters smaller than 8.816 μm and larger than 766 nm.</p> <p><i>Note: Please see the Particle Size Distribution Report Form.</i></p>	48858302
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Physical and Chemical Characteristics (Series 830, Group B)

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was

Particle Size Distribution Report Form

Item	Description
Identity of Test Material	
Composition	Silver-zinc zeolite; zeolite A ion exchange carrier with 3.5% ionic silver (Ag^+) and 6.5% ionic zinc (Zn^{++})
Source	Bactekiller AZ
Lot/Batch ID	File #20120405181657-9 (ultrasound), -8 (no ultrasound)
Sample Preparation	
Sample Amount	
Dispersion Medium	Water
Dispersion Equipment	Horiba LA-920 – circulation, with or w/o ultrasound
Equipment Power Rating	
Duration of Dispersion Treatment	Throughout measurement
Dispersion Verification	
Analytic Method	
Measurement Principle	Laser Diffraction Technology
Instrument/Model	Horiba LA-920
Software Version	3.26
Calculation Method	Arithmetic mean diameter; also specific surface area, median diameter, % at each diameter (discrete and cumulative); percentiles; mode diameter; residual R
Limits of Measurement (min/max)	0.020-2000 μm
Calibration or Standardization Procedure (reference materials)	
Precision: Repeatability or Reproducibility	
Results	
Distribution Basis (mass, number, or volume)	Volume
Mean Diameter (nm)	2193.7 (ultrasound), 2324.2 (no ultrasound)
10% size (μm)	1.35 (ultrasound), 1.39 (no ultrasound) (interpolated)
50% size (μm)	1.9947 (ultrasound), 2.1123 (no ultrasound)
90% size (μm)	3.2923 (ultrasound), 3.5394 (no ultrasound)
Min/max of Size Range (μm)	0.766 – 8.816 (ultrasound), 0.766 – 7.697 (no ultrasound)
% less than 0.1 μm	0.00 (none)
Additional Information/Comments	
Product Name: Bactekiller AZ (EPA Reg. No.82414-2). See MRID 48858302.	
Density: 2.2 g/cm ³ . See DP Barcode D157178, D169928.	